UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,054	10/15/2001	Nordine Cheikh	16517.256/38-21(15094)C	3580

28381 7590 08/28/2009

ARNOLD & PORTER LLP
ATTN: IP DOCKETING DEPT.
555 TWELFTH STREET, N.W.
WASHINGTON, DC 20004-1206

EXAMINER	
ALLEN, MARIANNE P	

ART UNIT	PAPER NUMBER
1647	

NOTIFICATION DATE	DELIVERY MODE
08/28/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IP.Docketing@aporter.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte NORDINE CHEIKH and JINGDONG LIU

Appeal 2009-002650[1]
Application 09/976,054
Technology Center 1600

Decided:[2] August 26, 2009

Before LORA M. GREEN, FRANCISCO C. PRATS, and
STEPHEN G. WALSH, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to plants and host cells transformed with nucleic acid molecules. The Examiner has rejected the claims as failing to meet the written description and enablement requirements. We have jurisdiction under 35 U.S.C. § 6(b).

---

[1] The real party in interest in this appeal is Monsanto Company.
[2] Oral argument was presented in this case on August 4, 2009.

We reverse.

STATEMENT OF THE CASE

Claims 12-17, 20-23, and 25 are pending (App. Br. 2).[3] Claims 12-17 stand allowed (*id.*). Claim 12 illustrates the subject matter recited in the allowed claims, and reads as follows:

> Claim 12. A substantially purified nucleic acid molecule comprising a nucleic acid sequence having the full-length sequence of SEQ ID NO: 5 or complement thereof.

"Expressed sequence tags, or ESTs are randomly sequenced members of a cDNA library" (Spec. 9). The nucleic acid molecule recited in claim 12 is one of the ESTs disclosed in the Specification (*see id.* at 19).

Based on comparisons between SEQ ID NO: 5 and nucleotide sequences from other plants, the Examiner found that SEQ ID NO: 5 encoded part of the maize adenine phosphoribosyl transferase enzyme (Non-Final Rejection 6 (September 27, 2006)). The Examiner further found that SEQ ID NO: 5 would be useful as a probe to isolate the full sequence of the gene encoding the enzyme, and concluded that claim 12 was allowable (*id.* at 7).

Claims 20-23 and 25 stand rejected and are on appeal (App. Br. 2). Claims 20 and 21 are representative of the appealed claims, and read as follows:

> Claim 20. A transformed plant comprising a recombinant nucleic acid molecule having the nucleic acid sequence of claim 12.
>
> Claim 21. A transformed host cell comprising a recombinant nucleic acid molecule having the nucleic acid molecule of claim 12.

---

[3] Appeal Brief filed May 1, 2008.

After allowing claim 12, the Examiner rejoined claims 20-23 and 25, which all depend directly or ultimately from claim 12, for prosecution (Non-Final Rejection 2 (March 6, 2007)). The Examiner rejected claims 20-23 and 25 as lacking written description and enablement (*id.* at 3-5) and maintained those rejections (*see generally* Final Rejection November 13, 2007). At Appellants' behest, those rejections are now before us for review.

The Examiner cites the following documents as evidence of unpatentability:

Moffatt US 5,777,018 Jun. 23, 1998

Quanhua Xing et al., *Cloning a second form of adenine phosphoribosyl transferase gene (TaAPT2) from wheat and analysis of its association with thermo-sensitive genic male sterility (TSGMS).* 169 Plant Science 37-45 (2005).

Genbank Accession No. U22442, 8 November 1995, Triticum aestivum (bread wheat).

WRITTEN DESCRIPTION

ISSUE

The Examiner presents the written description rejection of claims 20-23 and 25 as a new matter rejection (Ans. 3). The Examiner notes that the rejected claims were not original claims, but instead were introduced in an amendment (*id.* at 4). The Examiner finds that the portions of the Specification cited in that amendment as supporting the claims "do not disclose transformed host cells or transformed plants" (*id.*).

The Examiner finds that original claims 6, 7, and 11 did recite transformed plants, but notes that those claims "clearly contemplate and disclose plants transformed with nucleic acid molecules operably linked to

regulatory sequences and that express a protein" (*id.* at 6). In contrast, the Examiner urges, "[n]one of claims 20-23 and 25 requires that the nucleic acid be in association with regulatory sequences such as promoters and transformed plants having nucleic acid sequences in the absence of such regulatory sequences are not disclosed" (*id.*).

Based on an analysis of the relevant portions of Appellants' disclosure, the Examiner further finds that a "fair reading of the [S]pecification, including the originally filed claims, would readily convey to one of ordinary skill in the art that transformed host cells and transformed plants that have regulatory features for expression operably linked to the polynucleotide of interest would have been contemplated" (*id.* at 9). In contrast, the Examiner contends, the Specification "does not disclose the inclusion of sequences, particularly SEQ ID NO: 5, in a plant where they are not intended to be expressed and/or not in a construct suitable for that purpose" (*id.*).

The Examiner further contends that claims 21 and 22 recite transformed host cells that are not required to be isolated, and that therefore, those claims "embrace transgenic organisms. Claim 21 is not limited to a plant but encompasses any organism. Non-plant transgenic organisms are not contemplated" (*id.*).

The Examiner further urges that claim 25 "is directed to a transformed plant consisting of a single type of transformed host cell. In addition, the transformed plant of claim 25 consists of the transformed host cells of claim 21 which are not limited to plant cells. A plant of this type is not disclosed nor contemplated" (*id.* at 9-10).

Appellants contend that an ordinary artisan reading the Specification would "understand that Appellants had possession of transformed plants and host cells comprising a nucleic acid sequence having the full-length sequence of SEQ ID NO: 5 or complement thereof" (App. Br. 4). As support for the rejected claims, Appellants point to the Specification's disclosure that "'[o]ne or more of the nucleic acid molecules of the present invention may be used in plant transformation or transfection' and that '[e]xogenous genetic material may be transferred into a plant cell and the plant cell regenerated into a whole, fertile or sterile plant'" (*id.* at 6 (quoting Specification 82:18-20)). Appellants argue that "[a]lone, this is sufficient to satisfy the written description requirement of 35 U.S.C. § 112, first paragraph" (App. Br. 6).

Appellants further contend that the Specification's use of optional language, such as "may," when referring to the transformed plants' capacity to express proteins encoded by the exogenous nucleic acids, demonstrates that the Specification did not contemplate that expression was required (*id.* at 7). With respect to claim 21, Appellants argue that the Specification provides a written description of producing transgenic plant cells, fungal cells, mammalian cells, and bacterial cells (*id.* at 8). Appellants conclude, therefore, that the Examiner "has offered no evidence to demonstrate, in light of the Appellants' disclosure, why one of ordinary skill in the art would reasonably doubt that the invention encompassed by the claims has not been adequately described in the present disclosure" (*id.* at 9).

In view of the positions advanced by Appellants and the Examiner, the issues with respect to this rejection are whether Appellants have shown that the Examiner erred in finding that the Specification provides an

adequate written description for plants transformed with an exogenous nucleic acid having SEQ ID NO: 5 only when the exogenous nucleic acid has regulatory elements for expression operably linked to it, and whether Appellants have shown that the Examiner erred in finding that the Specification fails to provide adequate written description for a host cell transformed an exogenous nucleic acid having SEQ ID NO: 5.

FINDINGS OF FACT ("FF")

1. Claim 20 recites a transformed plant comprising a recombinant nucleic acid molecule with the full-length sequence of SEQ ID NO: 5 or a complementary sequence.

Claim 21 recites a transformed host cell comprising a recombinant nucleic acid molecule with the full-length sequence of SEQ ID NO: 5 or a complementary sequence.

2. The section of the Specification entitled "(a) Plant Constructs and Plant Transformants" begins on page 82 of the Specification. The section begins by explaining:

> (a) Plant Constructs and Plant Transformants
>
> One or more of the nucleic acid molecules of the present invention may be used in plant transformation or transfection. Exogenous genetic material may be transferred into a plant cell and the plant cell regenerated into a whole, fertile or sterile plant. Exogenous genetic material is any genetic material, whether naturally occurring or otherwise, from any source that is capable of being inserted into any organism.

(Spec. 82.)

3. The "Plant Constructs and Plant Transformants" section further explains:

> Transfer of a nucleic acid that encodes for a protein can result in overexpression of that protein in a transformed cell or transgenic plant. One or more of the proteins or fragments thereof encoded by nucleic acid molecules of the present invention may be overexpressed in a transformed cell or transformed plant. Particularly, any of the cytokinin pathway proteins or fragments thereof may be overexpressed in a transformed cell or transgenic plant. Such overexpression may be the result of transient or stable transfer of the exogenous genetic material.
>
> Exogenous genetic material may be transferred into a plant cell and the plant cell by the use of a DNA vector or construct designed for such a purpose. Design of such a vector is generally within the skill of the art (See, Plant Molecular Biology: A Laboratory Manual, Clark (ed.), Springier, New York (1997), the entirety of which is herein incorporated by reference).
>
> A construct or vector may include a plant promoter to express the protein or protein fragment of choice. A number of promoters which are active in plant cells have been described in the literature.

(Spec. 83.)

4. The Specification discloses that "[c]onstructs or vectors may also include with the coding region of interest a nucleic acid sequence that acts, in whole or in part, to terminate transcription of that region" and "may also include regulatory elements" (*id.* at 88).

5. The Specification discloses:

> There are many methods for introducing transforming nucleic acid molecules into plant cells. Suitable methods are believed to include virtually any method by which nucleic acid molecules may be introduced into a cell, such as by *Agrobacterium* infection or direct delivery of nucleic acid molecules such as, for example, by PEG-mediated

> transformation, by electroporation or by acceleration of DNA coated particles, etc . . . .

(*Id.* at 91.)

6. The Specification discloses:

> Any of the nucleic acid molecules of the present invention may be introduced into a plant cell in a permanent or transient manner in combination with other genetic elements such as vectors, promoters, enhancers etc. Further, any of the nucleic acid molecules of the present invention may be introduced into a plant cell in a manner that allows for overexpression of the protein or fragment thereof encoded by the nucleic acid molecule.

(*Id.* at 101.)

7. The Specification discloses that "one or more of the nucleic acids of the present invention may be introduced into a plant cell and transcribed using an appropriate promoter with such transcription resulting in the cosuppression of an endogenous cytokinin pathway protein" (*id.* at 102).

8. The Specification discloses the application of antisense techniques, and that gene "inactivation and its developmental effect can be manipulated by the choice of promoter for antisense genes or by the timing of external application or microinjection. Antisense can manipulate its specificity by selecting either unique regions of the target gene or regions where it shares homology to other related genes" (*id.* at 103).

9. The Specification discloses that "the activity of a cytokinin pathway protein in a plant cell may be reduced or depressed by growing a transformed plant cell containing a nucleic acid molecule whose non-transcribed strand encodes a cytokinin pathway protein or fragment thereof" (*id.*).

10. The Specification discloses:

> Exogenous genetic material may be transferred into a fungal cell. In a preferred embodiment the exogenous genetic material includes a nucleic acid molecule of the present invention having a sequence selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 711 or complements thereof or fragments of either or other nucleic acid molecule of the present invention. The fungal recombinant vector may be any vector which can be conveniently subjected to recombinant DNA procedures.

(*Id.* at 105.)

11. The Specification discloses:

> The present invention also relates to methods for obtaining a recombinant mammalian host cell, comprising introducing into a mammalian cell exogenous genetic material. In a preferred embodiment the exogenous genetic material includes a nucleic acid molecule of the present invention having a sequence selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 711 or complements thereof or fragments of either or other nucleic acid molecule of the present invention.

(*Id.* at 117-118.)

12. The Specification discloses:

> The present invention also relates to methods for obtaining a recombinant insect host cell, comprising introducing into an insect cell exogenous genetic material. In a preferred embodiment the exogenous genetic material includes a nucleic acid molecule of the present invention having a sequence selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 711 or complements thereof or fragments of either or other nucleic acid molecule of the present invention.

(*Id.* at 123.)

13. The Specification discloses:

> The present invention also relates to methods for obtaining a recombinant bacteria host cell, comprising introducing into a bacterial host cell exogenous genetic material.[] In a preferred embodiment the exogenous genetic material includes a nucleic acid molecule of the present invention having a sequence selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 711 or complements thereof or fragments of either or other nucleic acid molecule of the present invention.

(*Id.* at 131.)

PRINCIPLES OF LAW

As stated in *TurboCare Div. of Demag Delaval Turbomachinery Corp. v. General Elec. Co.*, 264 F.3d 1111, 1118 (Fed. Cir. 2001):

> The written description requirement and its corollary, the new matter prohibition of 35 U.S.C. § 132, both serve to ensure that the patent applicant was in full possession of the claimed subject matter on the application filing date. When the applicant adds a claim or otherwise amends his specification after the original filing date . . ., the new claims or other added material must find support in the original specification.

The test for determining whether a specification is sufficient to support a particular claim "is whether the disclosure of the application relied upon 'reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.'" *Ralston Purina Co. v. Far-Mar-Co, Inc.,* 772 F.2d 1570, 1575 (Fed.Cir.1985) (quoting *In re Kaslow,* 707 F.2d 1366, 1375 (Fed.Cir.1983)).

Thus, "[i]t is not necessary that the application describe the claim limitations exactly, but only so clearly that persons of ordinary skill in the art will recognize from the disclosure that appellants invented processes including those limitations." *In re Wertheim*, 541 F.2d 257, 262 (CCPA 1976) (citation omitted); *see also Purdue Pharma L.P. v. Faulding, Inc.*, 230

F.3d 1320, 1323 (Fed. Cir. 2000) ("In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue.").

Moreover:

> A claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language. That is because the patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before. Placed in that context, it is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention and to enable such a person to make and use the invention without undue experimentation.

Falkner v. Inglis, 448 F.3d 1357, 1366 (Fed. Cir. 2006) (quoting *LizardTech, Inc. v. Earth Resource Mapping, PTY, Inc.*, 424 F.3d 1336, 1345 (Fed.Cir.2005)); *see also Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005) ("It is not necessary that every permutation within a generally operable invention be effective in order for an inventor to obtain a generic claim, provided that the effect is sufficiently demonstrated to characterize a generic invention."); *also In re Anderson*, 471 F.2d 1237, 1242 (CCPA 1973) ("It is always possible to put something into a combination to render it inoperative. It is not the function of the claims to *exclude* all such matters but to point out what the combination is.").

ANALYSIS

We agree with Appellants that the Examiner erred in finding that the Specification provides an adequate written description for plants transformed with an exogenous nucleic acid having SEQ ID NO: 5 only

when the exogenous nucleic acid has regulatory elements for expression operably linked to it. We also agree with Appellants that the Examiner erred in finding that the Specification fails to provide adequate written description for a host cell transformed an exogenous nucleic acid having SEQ ID NO: 5.

Regarding claim 20 and the other claims reciting transformed plants and plant cells, the first paragraph of the section of the application entitled "Plant Constructs and Plant Transformants" states that "[o]ne or more of the nucleic acid molecules of the present invention may be used in plant transformation or transfection" (FF 2). The Specification then states that "[e]xogenous genetic material may be transferred into a plant cell and the plant cell regenerated into a whole, fertile or sterile plant. Exogenous genetic material is *any genetic material*, whether naturally occurring or otherwise, *from any source* that is capable of being inserted into any organism" (*id.* (emphases added)).

Given the disclosure that the inventive nucleic acid molecules can be used in plant transformation, we agree that the Specification would have conveyed to an ordinary artisan that Appellants possessed plants transformed with any of the disclosed nucleic acid sequences. Given the Specification's immediately following disclosure that *any* genetic material could be inserted into plants, we further agree that an ordinary artisan would have understood that the transforming nucleic acids need not be accompanied by any particular accessory elements, expression-associated, regulatory, or otherwise.

We note that the "Plant Constructs and Transformants" section includes significant discussion about expressing the proteins encoded by the inserted nucleic acids, as well as the use of promoters, terminators, and

expression-regulating elements (*see, e.g.,* FF 3-6). However, as Appellants point out, those discussions are presented using optional language about what elements *may* be included with the exogenous nucleic acid (*see id.*).

Given the optional nature of the expression-associated and regulatory elements, combined with the express disclosure that any nucleic acid can be inserted into plants, we are not persuaded that the overall context of the Plant Constructs and Transformants section would have conveyed to an ordinary artisan that Appellants possessed transformed plants only when the exogenous nucleic acid was accompanied by expression-associated or regulatory accessory elements. Nor are we persuaded that the Specification fails to demonstrate that Appellants possessed the transformed host cells recited in claim 21.

Claim 21 recites a transformed host cell comprising a recombinant nucleic acid molecule with the full-length sequence of SEQ ID NO: 5 or a complementary sequence. The Specification discloses that, in addition to plant cells, the inventive nucleic acids can be transferred to fungal, mammalian, insect, and bacterial cells (*see* FF 10-13).

While the claim might be read as encompassing transgenic organisms, a claim does not lack written description merely because it fails to explicitly exclude every conceivable undescribed embodiment it encompasses. *See Falkner v. Inglis*, 448 F.3d at 1366 ("A claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language. That is because the patent specification is written for a person of skill in the art . . . ."); *see also In re Anderson*, 471 F.2d 1237, 1242 (CCPA 1973) ("It is always possible to put something into a combination to render it

inoperative. It is not the function of the claims to *exclude* all such matters but to point out what the combination is.").

In the instant case claim 21 recites a host cell transformed with a nucleic acid. The Specification discloses that the inventive nucleic acids can be transferred to plant, fungal, mammalian, insect, and bacterial cells. We are therefore not persuaded that the disclosure fails to demonstrate possession of the subject matter recited in claim 21, or its dependent claims.

In sum, for the reasons discussed, we agree with Appellants that the Examiner erred in concluding that claims 20-23 and 25 lacked descriptive support. We therefore reverse the Examiner's written description rejection of those claims.

ENABLEMENT

ISSUE

Claims 20-23 and 25 stand rejected under 35 U.S.C. § 112, first paragraph, "as failing to comply with the enablement requirement" (Ans. 10). The Examiner finds that comparison of SEQ ID NO: 5, which encodes the maize adenine phosphoribosyl transferase, with known adenine phosphoribosyl transferases from other plants, demonstrates that SEQ ID NO: 5 contains a frame shift mutation (Ans. 12-13 (citing Xing, Moffatt, and Genbank Accession No. U22442)).

The Examiner therefore reasons that "[i]f SEQ ID NO: 5 was expressed, 59 amino acids of the maize adenine phosphoribosyl transferase fused to a random, not naturally occurring amino acid sequence would be produced due to the frameshift present in the nucleic acid sequence. A complete adenine phosphoribosyl transferase would not result" (Ans. 14). The Examiner further notes that the Specification "does not provide any

example of a transformed host cell or plant having the sequence of SEQ ID NO: 5" (*id.* at 15).

Based on these findings, the Examiner concludes that, to the extent the claims encompass embodiments where the host cell or plant expresses a protein, "the nucleic acid of claim 12 does not encode a complete or biologically active protein. The specification does not teach how to use such . . . transformed host cells or plants" (*id.*). The Examiner further concludes that, "[f]or those claim embodiments that merely require the presence of the nucleic acid in the host cell or plant but not in a context or form where any protein is expressed, the specification does not teach how to use such transformed host cells or plants" (*id.*).

Appellants contend that the Specification discloses the use of transformed host cells and plants "in connection with selectable and screenable markers" and in the context of cosuppression, and that "neither of these uses necessarily *requires* the expression of a protein or partial protein encoded by SEQ ID NO: 5" (Reply Br. 10). Moreover, Appellants argue, "at the very least, the claimed transformed host cells and plants may be used to replicate SEQ ID NO: 5. Such a use does not require that the claimed transformed host cells and plants encode a full length maize adenine phosphoribosyl transferase" (*id.*).

In view of the arguments advanced by Appellants and the Examiner, the issue with respect to this rejection is whether Appellants have shown that the Examiner erred in concluding that the Specification fails to teach an ordinary artisan how to use the claimed transformed plants and cells.

PRINCIPLES OF LAW

The Examiner bears the burden of establishing that practicing the full scope of the claimed subject matter would have required undue experimentation. *In re Wright*, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) ("[T]he PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application.").

Moreover, "[working] examples are not required to satisfy section 112, first paragraph." *In re Strahilevitz*, 668 F.2d 1229, 1232 (CCPA 1982). For example, in *Falkner v. Inglis*, the court affirmed this Board's conclusion that claims to a modified pox virus vaccine were enabled, despite the fact that the specification focused on viruses other than pox virus, provided no examples directed to pox virus, and discussed pox virus only in general terms relating to the inventive disclosure. *Falkner,* 448 F.3d at 1365.

Thus, as noted in *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003):

> The enablement requirement is often more indulgent than the written description requirement. The specification need not explicitly teach those in the art to make and use the invention; the requirement is satisfied if, *given what they already know*, the specification teaches those in the art enough that they can make and use the invention without "undue experimentation."

Id. at 1334 (emphasis added).

ANALYSIS

We agree with Appellants that the Examiner erred in concluding that the Specification fails to teach an ordinary artisan how to use the claimed transformed plants and cells. As Appellants point out, the Specification discloses using the recombinant nucleic acid molecule in cosuppression and antisense applications (FF 7-9), neither of which requires expression of a protein.

Moreover, given the Specification's disclosure that the inventive nucleic acids can be inserted into plants, plant cells, fungal cells, mammalian cells, insect cells, and bacterial cells (*see* FF 2 and 10-13), we agree with Appellants that, at the very least, an ordinary artisan would have recognized that plants and host cells could be used to replicate the recombinant nucleic acid. We are therefore not persuaded by the Examiner that the Specification fails to meet the "how to use" prong of the enablement requirement. Accordingly, we reverse the Examiner's rejection of claims 20-23 and 25 as lacking enablement.

SUMMARY

We reverse the Examiner's written description and enablement rejections of claims 20-23 and 25.

REVERSED

dm

ARNOLD & PORTER LLP
ATTN: IP DOCKETING DEPT.
555 TWELFTH STREET, N.W.
WASHINGTON, DC 20004-1206